

REMARKS

Claims 27-29, 33-34, and 50-52 are pending in this application, with claim 27 being independent.

Applicants submit that no new matter is presented herein.

Applicants respectfully request reconsideration and withdrawal of the outstanding rejections in view of the remarks presented below.

The Presently-Claimed Invention

The presently-claimed invention relates, generally, to a packaged antimicrobial elastomeric article that is essentially free of powder and starch, and is coated with at least one wetting agent, at least one antifoaming agent, and at least one antimicrobial agent. The package comprises a desiccant for reducing the relative humidity in the vicinity of the elastomeric article to less than the ambient relative humidity. The packaged elastomeric article is capable of causing at least 1 log₁₀ reduction of the initial number of microorganisms that come into contact with the treated glove surface in five minutes of contact after being stored and/or transported for at least 45 days.

The claimed elastomeric articles beneficially minimize or reduce cross-contamination that can occur as a result of contact by a wearer or user of the article with more than one other object. When the antimicrobial agent is applied to the surface in contact with the wearer's hand, the elastomeric articles also inhibit growth of skin flora. See paragraph [0034]. The package system, which includes a moisture-resistant water-vapor impermeable barrier and a desiccant, reduces relative humidity and maintains said reduced relative humidity in the vicinity of the antimicrobial elastomeric article. See paragraph [0037]-[0038].

Rejection under 35 U.S.C. § 103(a)

Claims 27-31, 33-34, 43-46, 48-49 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,133,090 ("Modak") in view of U.S. Application No. 2002/0152538 ("McDevitt"), further in view of U.S. Patent No. 5,322,161 ("Shichman") and U.S. Patent No. 5,357,636 ("Dresdner").

Applicants respectfully traverse this rejection.

The Office Action relies upon Modak for disclosing an antimicrobial elastomeric article that includes anti-infective agents such as chlorhexidine salts and a lubricating agent. The coating of Modak may further comprise quaternary ammonium halides such as benzalkonium chloride, and biomedically acceptable polymers such as polyurethanes and silicones. The polymers may be used to "minimize the possibility of lubricating agent being released from the glove surface and to provide lubricity due to the nature of the polymeric component." See col. 3, lines 1-4.

The Office Action admits that Modak does not disclose a process for extending antimicrobial activity.

McDevitt is cited for disclosing a finger glove that is contained in a package "...in order to preserve any additives applied to the finger glove or otherwise to maintain the finger glove in a sterile environment." See paragraph [0189]. The packaging materials can include ethylene vinyl alcohol (EVA) film, film foil laminates, metalized films, multi-layered plastic films. See paragraph [0189].

Shichman is cited for disclosing adding a dessicant to a package to reduce moisture. The packaging materials can include laminate films including a polymeric base layer, an intermediate inorganic thin film layer, and a heat sealable coating layer. See col. 4, lines 58-63. The desiccants can include those described in, and preferred desiccants include crystalline aluminosilicates (such as zeolite Z-12) and silica gels. See col. 6, lines 24-26.

Dresdner is also cited for disclosing sterile packaging of elastomeric gloves, and use of chlorhexidine gluconate and benzalkonium chloride as antiseptic agents.

Applicants submit that the combination of Modak, Dresdner, McDevitt, and Schichman fails to disclose or suggest the presently-claimed invention. Testing was conducted to determine the antimicrobial properties of an elastomeric article prepared in accordance with the disclosure of Modak (specifically, natural rubber latex gloves prepared in accordance with Example 1 of Modak, and then coated with an antimicrobial agents in accordance with Example 4 of Modak).¹ These gloves were placed in a package in accordance with the disclosure of McDevitt (specifically, three different packages were tested, Rollprint ClearFoil® film, Rollprint Triad® C film, and Amcor aluminum foil film), and including a desiccant in accordance with the disclosure of Schichman (specifically, Tri-Sorb® aluminosilicate zeolite).

The packaged antimicrobial elastomeric articles produced in accordance with the disclosures of Modak, Dresdner, McDevitt, and Schichman were aged for 45 days, and then tested to assess the log₁₀ reduction of the initial number of microorganisms that come into contact with the treated glove surface after five minutes of contact. Unaged (fresh) gloves were also tested to assess the log₁₀ reduction of the initial number of microorganisms that come into contact with the treated glove surface after five minutes of contact. The packaged antimicrobial elastomeric articles produced in accordance with the disclosures of Modak, Dresdner, McDevitt, and Schichman failed to cause at least 1 log₁₀ reduction of the initial number of microorganisms that come into contact with the treated glove surface in five minutes of contact after being stored and/or transported for at least 45 days. This is demonstrated by the test data set forth in the Declaration of Nicholas R. Krogman, Ph.D. under 37 C.F.R. § 1.132, which is being submitted herewith.

Applicants' test data set forth in the present specification, and particularly in Examples 3 and 4, has been condensed into the tables presented in the Appendix attached to this Amendment. This data demonstrates that the presently-claimed

¹ With the exception of Example 4, all of the coatings disclosed in Modak contained powder or starch, which is outside the scope of the presently-claimed invention. Example 4 related to a glove coated with 2% hydroxyethylcellulose, *optionally* 1% zinc oxide powder, and 1-2% CHG, and therefore did not require the inclusion of powder or starch.

packaged antimicrobial elastomeric articles cause at least 1 log₁₀ reduction of the initial number of microorganisms that come into contact with the treated glove surface in five minutes of contact after being stored and/or transported for at least 45 days. Applicants submit that this difference in the antimicrobial effectiveness provided by the packaged antimicrobial elastomeric articles of the presently-claimed invention is unexpected in view of the reduction in antimicrobial effectiveness experienced by the packaged antimicrobial elastomeric articles produced in accordance with the disclosures of Modak, Dresdner, McDevitt, and Shichman following aging. Applicants further submit that the testing set forth in the present specification encompasses the use of natural rubber as well as nitrile, variations in the type and amount of antimicrobial agent used to coat the elastomeric article, use of different package materials, and use of different desiccants demonstrates that the antimicrobial effectiveness of the packaged elastomeric articles of the presently-claimed invention is a general phenomenon, and is not specific to the material from which the glove is formed, the antimicrobial agent used, the packaging used, or the desiccant used.

For at least these reasons, Applicants again submit that one skilled in the art would not look to Dresdner, McDevitt, and/or Shichman to remedy the deficiencies of Modak with respect to the presently-claimed invention.

Applicants respectfully submit that the combination of Modak, Dresdner, McDevitt, and Shichman fails to disclose or suggest the presently-claimed packaged antimicrobial elastomeric articles. Further, nothing in the disclosures of Modak, McDevitt, and Shichman would lead one skilled in the art to modify them to arrive at the presently-claimed invention without the benefit of hindsight reconstruction based on Applicants' disclosure. Applicants therefore submit that claims 27-29, 33-34, and 50-52 are not unpatentable over the combination of Modak, McDevitt, and Shichman, and respectfully request withdrawal of this rejection.

CONCLUSION

In view of the foregoing, reconsideration of the application, withdrawal of the outstanding rejections, allowance of claims 27-29, 33-34, and 50-52, and the prompt issuance of a Notice of Allowance are respectfully requested.

Should the Examiner believe that anything further is necessary in order to place this application in better condition for allowance, the Examiner is requested to contact the undersigned at the telephone number listed below.

In the event that additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefore are hereby authorized to be charged to our Deposit Account No. 01-2300 referencing docket number **029714.00017**.

Respectfully submitted,



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Attachments: Appendix
Declaration of Nicholas R. Krogman,
Ph.D. under 37 C.F.R. § 1.132

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APPENDIX

As described on pages 14-15 of the specification, an antimicrobial solution for coating a glove surface was prepared by blending 10 g of Surfynol TG and 5 g of BYK-348 into 485 g of deionized water to form a wetting solution. The wetting solution was then diluted with deionized water and antimicrobial agents were added in desired amounts (see page 16).

Gloves were coated using the process described on pages 15-16 of the specification. Antimicrobial testing and aging were carried out based on the disclosure found on pages 16-19 of the specification.

Antimicrobial efficacy data was obtained for unaged gloves, and for gloves that were aged for 45 days at 40°C and 70% relative humidity was presented in the tables included in Examples 3 and 4 of the specification. This data is summarized below:

Table 3A

<i>P. aeruginosa</i> LR	<i>S. aureus</i> LR	Conditioning
4.94	4.76	Fresh
3.23	3.80	45 days @ 40°C

See Example 3, Table 3A, pages 22-23. Data for natural rubber gloves coated with antimicrobial solution containing 3% total solids content, and using a combination of BKC:CHG in a ratio of 2:1; package was a nylon/aluminum foil/LDPE (NFE) pouch from Amcor, of Abbotsford Australia; desiccant was a calcium sulfate desiccant bag containing 2.5g of desiccant, made by Drierite, of Xenia, Ohio.

Table 4A

<i>P. aeruginosa</i> LR	<i>S. aureus</i> LR	Conditioning
5.87	5.78	Fresh
5.64	5.21	45 days @ 40°C

See Example 4, Table 4A, pages 25-26. Data for nitrile gloves coated with antimicrobial solution containing 3% total solids content, and using a combination of BKC:CHG in a ratio of 2:1; package was a nylon/aluminum foil/LDPE (NFE) pouch from Amcor, of Abbotsford Australia; desiccant was a calcium sulfate desiccant bag containing 2.5g of desiccant, made by Drierite, of Xenia, Ohio.

Table 4B

<i>P. aeruginosa</i> LR	<i>S. aureus</i> LR	Conditioning
4.00	5.33	Fresh
3.97	5.16	45 days @ 40°C

See Example 4, Table 4B, pages 26-27. Data for nitrile gloves coated with antimicrobial solution containing 1.5% total solids content, and using a combination of BKC:CHG in a ratio of 2:1; package was a PET/aluminum foil/LDPE (RFE) pouch from Amcor, of Abbotsford Australia; desiccant was a clay Desi Pak made by Sud-Chemie, of Belen, New Mexico.

Table 4C

<i>P. aeruginosa</i> LR	<i>S. aureus</i> LR	Conditioning
5.12	5.20	Fresh
4.87	5.18	45 days @ 40°C

See Example 4, Table 4C, pages 27-28. Data for nitrile gloves coated with antimicrobial solution containing 1.25% total solids content, and using a combination of BKC:CHG in a ratio of 2:1; package was a PET/aluminum foil/LDPE (RFE) pouch from Amcor, of Abbotsford Australia; desiccant was a clay Desi Pak made by Sud-Chemie, of Belen, New Mexico.

Table 4D

<i>P. aeruginosa</i> LR	<i>S. aureus</i> LR	Conditioning
4.38	4.79	Fresh
2.62	3.73	45 days @ 40°C

See Example 4, Table 4D, pages 28-29. Data for nitrile gloves coated with antimicrobial solution containing 1.5% total solids content, and using a combination of Bardac:CHG in a ratio of 2:1; package was a PET/aluminum foil/LDPE (RFE) pouch from Amcor, of Abbotsford Australia; desiccant was a clay Desi Pak made by Sud-Chemie, of Belen, New Mexico.